

Exhibit 300: Capital Asset Plan and Business Case Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview (All Capital Assets)

1. Date of Submission: 2010-03-17 14:09:40

2. Agency: 009

3. Bureau: 10

4. Name of this Investment: FDA Information and Computing Technologies for the 21st Century (ICT21)

5. Unique Project (Investment) Identifier: 009-10-01-03-01-0031-00

6. What kind of investment will this be in FY 2011?: Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

7. What was the first budget year this investment was submitted to OMB? *

8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.

Development of new information technologies, driven by accelerating computational processing & substantial growth in data volume, is causing transformation to all aspects of the FDA operations. New types & vastly larger quantities of data to be processed by the FDA, from multiple clinical & diagnostic endpoints from industry submissions & collaborations with other research sources, reuse of existing data within & among the FDA centers & other government agencies (i.e. NIH, CMS, CDC, VA, DoD, etc.), & outside entities including foreign countries, are examples of the complexity & number of information sources the FDA handles today. The number of sources & data elements increases as the need for complex inputs for safety evidence & efficacy information, genomics, metabolic network & clinical trials modeling, data markers type data, integrated data & networks, & food imports expands. The FDA is increasing its use of electronic health records data to acquire pertinent information for its pharmacovigilance efforts causing expanded participation in programs & initiatives to define of the records standards & networks to assure appropriate data are gathered for use in such activities as safety & efficacy, & genomics & data markers. To meet these challenges, the FDA is modernizing its capacity & communication capabilities by creating an agency-wide bioinformatics IT platform. The ICT21 Initiative designs & builds this purpose driven, data centric environment for the FDA. The initiative increases the Agency's capabilities to: respond to emerging technologies & challenges, strengthen product development & approval, improve manufacturing & product quality, strengthen post-approval surveillance & safety, support electronic prescribing, & improve clinical decision making. Results are achieved by collecting & combining clinical & other important & pertinent data from industry, government agencies & outside entities into integrated databases & networks to expand the scientific computations & computational sciences at the FDA. The FDA continues to widen the use of analytics for large datasets which integrate multiple clinical & diagnostic endpoints, through increased use of clustering & grid computing to improve collaboration among & within entities interacting with the FDA. The new ICT21 bioinformatics platform supports the FDA's growing mission within 2–10 years & the PMA goal-Expanded e-Government - Disaster Management, & the DHHS goal of increasing scientific R&D.

- a. Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned) alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

9. Did the Agency's Executive/Investment Committee approve this request? *

a. If "yes," what was the date of this approval? *

10. Contact information of Program/Project Manager?

- Name: *
- Phone Number: *
- Email: *

11. What project management qualifications does the Project Manager have? (per FAC-P/PM)? *

- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):

Financial management system name(s)	System acronym	Unique Project Identifier (UPI) number
*	*	*

a. If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one): *

- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES (REPORTED IN MILLIONS) (Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions)									
	PY1 and earlier	PY 2009	CY 2010	BY 2011	BY+1 2012	BY+2 2013	BY+3 2014	BY+4 and beyond	Total
Planning:	*	*	*	*	*	*	*	*	*
Acquisition:	*	*	*	*	*	*	*	*	*
Subtotal Planning & Acquisition:	*	*	*	*	*	*	*	*	*
Operations & Maintenance:	*	*	*	*	*	*	*	*	*
Disposition Costs (optional):	*	*	*	*	*	*	*	*	*
SUBTOTAL:	*	*	*	*	*	*	*	*	*
Government FTE Costs should not be included in the amounts provided above.									
Government FTE Costs	*	*	*	*	*	*	*	*	*
Number of FTE represented by Costs:	*	*	*	*	*	*	*	*	*
TOTAL(including FTE costs)	*	*	*	*	*	*	*	*	*

2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:

*

Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table 1: Contracts/Task Orders Table

Contract or Task Order Number	Type of Contract/Task Order (In accordance with FAR Part 16)	Has the contract been awarded (Y/N)	If so what is the date of the award? If not, what is the planned award date?	Start date of Contract/Task Order	End date of Contract/Task Order	Total Value of Contract/Task Order (M)	Is this an Interagency Acquisition? (Y/N)	Is it performance based? (Y/N)	Competitively awarded? (Y/N)	What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A)	Is EVM in the contract? (Y/N)
FY09 - FY11 HHSF223200750011C: 8A/Small Business Award	T&M: Time & Materials	Y	2007-05-15	2007-05-15	2009-05-14	\$0.2	*	*	*	*	*
FY09 - FY11 HHSF223200750014C : 8A/Small Business Award - Establish the Service Oriented Architecture framework.	T&M: Time & Materials	Y	2007-05-29	2007-06-01	2008-11-30	\$0.4	*	*	*	*	*
FY09 - FY11 HHSF223200750680G Project Management Support - Establish ICT21 PMO to manage Bioinformatics initiatives	T&M: Time & Materials	Y	2007-10-01	2007-10-15	2008-09-30	\$0.6	*	*	*	*	*
HHSF223200850016I	CPAF: Cost Plus Award Fee	Y	2008-09-29	2008-09-29	2010-09-29	\$3.9	*	*	*	*	*
HHSF223200850017I	CPFF: Cost Plus Fixed Fee	Y	2008-09-29	2008-09-30	2013-09-20	\$35.0	*	*	*	*	*
HHS223200850014I	FFP: Firm Fixed Price	Y	2008-09-29	2008-09-30	2013-08-31	\$592.4	*	*	*	*	*
HHSF223200850020I	FFP: Firm Fixed Price	Y	2009-03-13	2009-04-01	2010-12-31	\$0.9	*	*	*	*	*
HHSF223200830059C	T&M: Time & Materials	Y	2008-09-23	2008-09-23	2009-09-23	\$3.5	*	*	*	*	*

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

*

3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements? *

a.If "yes," what is the date? *

Section D: Performance Information (All Capital Assets)

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2008	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of bioinformatics platform requirements and design documented and approved.	25%	100%	100%
2008	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of bioinformatics customer availability requirements documented.	25%	95%	95%
2008	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of external bioinformatics collaboration opportunities identified.	0	2	2
2008	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	10%	25%	25%
2009	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of bioinformatics platform phase 1 migration complete.	0%	100%	0%
2009	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of electronic product safety information available	5%	10%	0%
2009	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of bioinformatics collaboration internal initiatives piloted	0	2	0
2009	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	10%	20%	0%

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
2010	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of bioinformatics platform phase 2 migration complete.	0%	100%	0%
2010	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of electronic product safety information available	20%	30%	0%
2010	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of bioinformatics collaboration external initiatives piloted	0	2	0
2010	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	50%	60%	0%
2011	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of bioinformatics platform phase 3 migration complete.	0%	100%	0%
2011	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of electronic product safety information available	30%	40%	0%
2011	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of bioinformatics collaboration internal and external initiatives in production.	0	4	0
2011	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	60%	70%	0%
2012	S.O. 4.2 - Increase basic scientific knowledge to	*	*	% of legacy systems disposed	0%	50%	0%

Table 1: Performance Information Table

Fiscal Year	Strategic Goal(s) Supported	Measurement Area	Measurement Grouping	Measurement Indicator	Baseline	Target	Actual Results
	improve human health and development						
2012	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of electronic product safety information available.	40%	50%	0%
2012	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of bioformatics collaboration internal and external initiatives in production.	4	6	0
2012	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	70%	80%	0%
2013	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of legacy systems disposed	50%	100%	0%
2013	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	% of electronic product safety information available.	50%	60%	0%
2013	S.O. 4.2 - Increase basic scientific knowledge to improve human health and development	*	*	number of bioformatics collaboration internal and external initiatives in production.	6	8	0
2013	S.O. 4.4 - Communicate and transfer research results into clinical, public health and human services practice	*	*	% of electronic safety reports for fda regulated products utilizing hl7 individual case safety report.	80%	90%	0%

Part II: Planning, Acquisition And Performance Information

Section A: Cost and Schedule Performance (All Capital Assets)

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Plan Program Mgmt Office	\$0.3	\$0.3	2007-05-14	2007-05-14	2007-09-30	2007-09-30	100.00%	100.00%
Establish and implement Program Mgmt Office	\$0.9	\$1.0	2007-10-01	2007-10-01	2008-09-30	2008-09-30	100.00%	100.00%
Perform Program Mgmt Functions	\$0.9	\$0.7	2008-10-01	2008-10-01	2009-09-30	2009-09-30	100.00%	100.00%
Perform Program Mgmt Functions	\$0.8	\$0.2	2009-10-01	2009-10-01	2010-09-30		25.00%	25.00%
Perform Program Mgmt Functions	*	*	2010-10-01		2011-09-30		0.00%	0.00%
Bioinformatics Transition Plan complete (Phase 1)	\$1.3	\$1.2	2007-08-01	2007-07-02	2007-10-31	2008-01-31	100.00%	100.00%
Detailed Alternatives Analysis Complete	\$1.0	\$1.1	2007-09-04	2007-08-20	2008-02-28	2008-03-11	100.00%	100.00%
Bioinformatics Transition Plan complete (Phase 2)	\$2.6	\$3.0	2007-11-01	2008-07-01	2009-01-30	2009-01-30	100.00%	100.00%
Bioinformatics Recovery site preparation complete	\$1.6	\$1.6	2007-07-02	2007-07-02	2008-01-30	2008-04-01	100.00%	100.00%
Bioinformatics design complete	\$1.1	\$1.4	2008-01-01	2008-10-01	2008-06-30	2009-08-01	100.00%	100.00%
First Phase - Bioinformatics Platform Migration complete	\$17.7	\$15.0	2008-07-01	2008-09-01	2009-07-31	2009-09-01	100.00%	100.00%
Second Phase - Bioinformatics Platform Migration complete	\$16.2	\$15.1	2009-08-03	2009-08-15	2010-03-31	2010-03-31	100.00%	80.00%
Third Phase - Bioinformatics Platform Migration complete	*	*	2010-04-01		2011-07-29		25.00%	0.00%
FY09	\$3.8	\$0.0	2009-08-03	2009-09-01	2009-09-30		100.00%	50.00%

1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline								
Description of Milestones	Planned Cost (\$M)	Actual Cost (\$M)	Planned Start Date	Actual Start Date	Planned Completion Date	Actual Completion Date	Planned Percent Complete	Actual Percent Complete
Operations and Maintenance Support								
FY10 Operations and Maintenance Support	\$5.1	\$1.3	2009-10-01	2009-10-01	2010-09-30		25.00%	25.00%
FY11 Operations and Maintenance Support	*	*	2010-10-01		2011-09-30		0.00%	0.00%

* - Indicates data is redacted.